Outlook

Naval Medical Research and Development Command

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On The Cutting Edge of Medical Research Today *December 1991*

MEDICAL LABORATORY COLOCATION AND CONSOLIDATION

by CAPT Raymond L . Chaput, MSC, USN, Special Assistant for BUMED Liasion

In 1989, the President directed DoD to allocate scarce defense dollars to the most urgent National Security Requirements. In response to this Presidential request, DOD, in October 1989, issued Defense Management Report Decision 922 (DMRD-922) tasking the services to consolidate R&D laboratories and T&E facilities. Several intra-service consolidation studies were initiated under the title of Project Reliance. In response to Project Reliance, each service proposed some degree of intra- and inter-service consolidation.

In February 1990, the Armed Services Biomedical Research and Evaluation Management (ASBREM) Committee initiated a study of the medical laboratories.

This study ultimately led to the issuance of Memoranda of Agreement (MOA) to consolidate the infectious disease program and to colocate several laboratories. The MOA were presented to and approved by RADM Miller, the Navy's representative to Project Reliance.

The ASBREM vision leading to these realignments was to:

- Preserve mission capabilities
- Enhance the reliance of one service on another for technology development
- Preserve and nurture a world-class technology base
- Provide an RDT&E environment which promotes recruitment, retention and career progression of quality personnel
- Increase the effectiveness, efficiency and productivity of the services' medical RDT&E programs
- Streamline command & control
- Reduce costs of RDT&E
- Obtain the best return on investment
- Facilitate resource allocation through greater emphasis on tri-service planning and program stability

Cont. on pg. 2

INSIDE THIS ISSUE:

MEDICAL LABORATORY COLOCATION AND CONSOLIDATION

Cont. from pg. 1

The realignment of the medical laboratories was also proposed to the Base Realignment and Closure Commission (BRAC) in order to take advantage of funding available under the BRAC Act for military construction. The BRAC accepted all the realignments except the NBDL and EMR moves and incorporated them in their document of July 1991, which has since been approved by the President and Congress.

Slated to begin in 1993 and be completed by 1997 are the following:

- The Infectious Disease programs at the Naval Medical Research Institute (NMRI) and at the Walter Reed Army Institute of Research (WRAIR) will be consolidated at the new WRAIR.
- The dental programs currently at the Naval Dental Research Institute (NDRI) and at the Army Institute of Dental Research (USAIDR) will be colocated at NDRI.
- The blood programs currently at NMRI and the Letterman Army Institute of Research (LAIR) will be colocated at NMRI.
- The programs on bioeffects of electromagnetic radiation currently at the Naval Aerospace Medical Research Laboratory (NAMRL), WRAIR, LAIR, and the Air Force Armstrong Aerospace Medical Research Laboratory (AAMRL) will be colocated at AAMRL.
- The biodynamics programs currently at the Naval Biodynamics Laboratory (NBDL), AAMRL, and the Army Aeromedical Research Laboratory (USAARL) will be colocated at AAMRL.
- The toxicology programs currently at the U.S. Army Biomedical Research and Development Laboratory (USABRDL) and AAMRL will be colocated at AAMRL.

As a result of these realignments, LAIR, USABRDL, USAIDR, and NBDL will close and approximately 200 personnel authorizations will be eliminated.

NAVY LABORATORIES AFFECTED:

NMRI	Naval Medical Research Institute, Bethesda, MD
NDRI	Naval Dental Research Institute, Great Lakes, IL
NAMRL	Naval Aerospace Medical Research Laboratory, Pensacola, FL
NBDL	Naval Biodynamics Laboratory, New Orleans, LA

ARMY LABORATORIES AFFECTED:

WRAIR	Walter Reed Army Institute of Research, Washington, DC
USAIDR	U.S. Army Institute of Dental Research, Washington, DC
LAIR	Letterman Army Institute of Research, San Francisco, CA
USAARL	U.S. Army Aeromedical Research Laboratory, Ft. Rucker, AL
USABRDL	U.S. Army Biomedical Research & Development Laboratory, Ft. Detrick, MD

AIR FORCE LABORATORIES AFFECTED:

AAMRL	Armstrong Aerospace Medical Research Laboratory, Wright Patterson AFB and Brooks AFB

Medical Laboratory Colocation and Consolidation

PROGRAM	CURRENT LOCATION	NEW LOCATION
Infectious Disease	NMRI, WRAIR	WRAIR
Dental	NDRI, USAIDR	NDRI
Blood	NMRI, LAIR	NMRI
Electromagnetic Radiation	NAMRL, WRAIR, LAIR, AAMRL	AAMRL
Biodynamics	NBDL, AAMRL, USAARL	AAMRL
Toxicology	USABRDL, AAMRL	AAMRL

STRATEGIC PLANNING UPDATE: First Steps to Establishing a Corporate Structure

by CAPT R.W. Gaugler, Executive Officer

NMRDC's most recent Strategic Planning Meeting was held on 17-20 September in Bethesda, MD. Participants at this meeting, including the NMRDC senior staff and the laboratories' COs, OICs and Scientific Directors, were charged with further defining specific actions necessary for implementing our third strategic goal: establishment of a corporate structure that maximizes productivity and efficiency (Outlook August 1991).

As a prelude to our discussions, RADM Hugh P. Scott, MC, USN, who recently assumed the position of BUMED-02, addressed the group and shared his thoughts on the future opportunities and challenges of medical R&D.

Similar presentations were provided by high level officials from three offices involved in the funding and oversight of our programs: Dr. James DeCorpo, the new Director of the Office of Advanced Technology, who administers all 6.3A programs; Mr. Glenn Spalding of the Office of Naval Technology for the 6.2 program; and Dr. Gene Silva of the Office of Naval Research for the 6.1 programs.

Each noted the potentially austere climate for resources in the coming years, but indicated that opportunities would still be available for high quality research.

The meeting's real work began with a briefing by the Strategic Planning Advisory Group on the vast amount of data they collected and analyzed to permit deliberations on defining our optimal corporate structure.

The main agenda topic was abruptly interrupted on the first day of the meeting, however, by the receipt of a draft memorandum prepared for signature of the Deputy Secretary of Defense (DEPSECDEF). The memorandum essentially directed that all medical efforts (clinical and research) of the Navy, Army, and Air Force be consolidated and placed under the control of the Assistant Secretary of Defense for Health Affairs.

A rapid response was needed and the group immediately turned its attention to developing a position that NMRDC would recommend to higher authority on the proposed changes in DOD medical RDT&E operations.

It was particularly fortunate that this issue arose during the time of the Strategic Planning meeting, as the NMRDC staff was able to obtain input for our response from the full breadth of our senior leadership. It also provided, for attendees from the laboratories, some insight into Washington crisis management!

At the present time, the impact of the DEPSECDEF memorandum is unclear. A high level DOD group has been charged to study the alternatives, and final decisions on these issues are pending until their findings and recommendations are reported in January 1992.

Following that day-long *firefight,* discussions refocused on a complete analysis of several proposed alternatives for a corporate structure under which we could operate and grow in the expected resource-limited environment.

Cost effectiveness and projected impact on research quality were important considerations in judging these alternatives. The group evaluated the program areas in-depth, the scientific personnel involved in each program area, and the expertise of our professional staffs. Every program was appraised according to a High/Low estimate of the value of the program to the Navy and to others; its access to important or unique assets; its scientific reputation; and its strength in scientific leadership, personnel availability, and adequate facilities. Each program was viewed for its possible need to be located in a particular geographical area due to facility requirements or necessary coordination with operational units.

Important in these analyses were the benefits that might accrue in terms of increasing critical scientific mass and decreasing overhead or administrative burden compared to costs that would be incurred in terms of program disruption.

Based on their analyses, the group agreed on the benefit of a future consolidation of programs into a large, central laboratory, which also would assume the headquarters functions of NMRDC. In addition to the central laboratory, detachments would be created to accomplish programs that are related to a specific geographic area.

The next Strategic Planning meeting, planned to be held during 9-11 December, will expand on this plan and begin to formulate actions to implement our other strategic goals and formalize a written NMRDC Strategic Plan.

VIEW FROM THE TOWER

By CAPT E.T. Flynn, Commanding Officer

During the past several months, it has become clear that the environment in which we conduct medical research in the Navy today will change dramatically. You are all aware of the tri-service research consolidation efforts that began in 1989. Through several iterations, these consolidation efforts developed into Project Reliance in which the three services agreed to rely on each other for certain aspects of research. For Navy medical research, the results of Project Reliance were five Memoranda of Agreement in which the Navy agreed to colocate or consolidate infectious disease, blood, EMR, dental and biodynamics research with the Army or Air Force.

We are now faced with a larger challenge. On the first of October 1991, the Under Secretary of Defense, Mr. Atwood, issued a memorandum to the Services entitled "Strengthening the Medical Functions of the Department of Defense". In essence, this memo assigns responsibility for all direct health care within the Services to the Assistant Secretary of Defense for Health Affairs.

There are two important paragraphs in this memo for us. In paragraph 3 it states, "... *all funding for DOD medical activities, including operation and maintenance, procurement, research and development, and CHAMPUS .... shall be consolidated into a single defense medical appropriations account...*".

This statement effectively removes medical research and development money from the Services and creates the potential for research dollars to have to compete head-to-head with direct health care dollars in the planning and budgeting process.

Paragraph 6 of the memo reads as follows, "*The Assistant Secretary of Defense for Health Affairs, the Assistant Secretary of Defense for Program Analysis and Evaluation, the Director of Defense Research and Engineering, and the Director of Administration and Management, in coordination with the Secretaries of the Military Departments, shall review jointly alternatives for the organization of the Department of Defense for the conduct of medical-related research, including the alternative of consolidating the various medical-related research components of the Department under the Uniformed Services University of the Health Sciences, and shall report their findings and recommendations to the Deputy Secretary of Defense within 120 days of this memorandum.*"

I am not certain where Mr. Atwood's memo is going to take us. The potential for a significant change in our system is very great. With the 120 days deadline coming at the end of January, the pace of activity has been intense with all sides developing positions and looking at the pros and cons of possible alternatives.

We are trying to be as proactive as possible. Our goal is to develop a structure that will satisfy DOD's need for program consolidation without sacrificing Navy focus or responsiveness. In this, we have very strong support from the Surgeon General and the Chief of Naval Research. Both feel that the NMRDC system has been productive, cost effective, and extremely responsive to Fleet/Marine Corps needs.

I had planned to discuss our strategic plan in this issue. As CAPT Gaugler notes on page 3, the commanding officers and scientific directors met in mid-September with the goal of drafting the final strategic plan. They were not successful in completing this task because of the *fire drill* provoked by the issuance of a draft copy of Mr. Atwood's memorandum. Very significant progress was made, however, on all the important aspects of the plan. Another strategic planning meeting is scheduled for early December. At that time we will have time to review where we stand with regard to Mr. Atwood's memorandum, decide what additional steps should be taken, and assess what alterations may be necessary in our strategic plan.

NAVY MICROBIOLOGIST ASSIGNED TO ONR-EUROPE

The Naval Medical Research Institute (NMRI) has initiated a collaborative effort with researchers at the Chemical and Biological Defence Establishment (CBDC), Porton Down, United Kingdom, to work on developing the rapid detection of biological warfare agents by Polymerase Chain Reaction (PCR) assays.

NMRDC recently completed the administrative procedures to place a NMRI microbiology billet in London, attached to ONR-Europe. LTjg Malcolm Johns, MSC, USNR, who is currently completing Officer Indoctrination School at Newport, Rhode Island, has been recruited to fill this position.

LTjg Johns' responsibilities will be to provide NMRI investigators with DNA probes against specific BW threat agents for use in the development of PCR assays. Once these PCR assays have been developed, he will then confirm their effectiveness in detecting live BW threat agents using the CBDE facilities at Porton Down.

CRAFTING THE CORPORATE ENVIRONMENT: Strengthening the Relationship Between the Headquarter's RAMs and the Managers and Investigators at the Laboratories

by Christine Eisemann, Associate Director for Research Management

One of NMRDC's long range goals is to create a corporate environment characterized by open participation, cooperative communication, and participative decision-making (Outlook, Aug 1991).

As a step toward this goal, during July 1991, the NMRDC Strategic Planning Advisory Group took a look at the jobs of the headquarter's Research Area Managers (RAMs) as seen by the RAMS, the laboratory managers and the research scientists.

A questionnaire was developed based on a list of job tasks provided by the RAMs. Tasks were grouped into seven major categories:

1. Development of the research program
2. Review of program progress
3. Defense of the program
4. Maintainence of scientific currency
5. Identification of new research topics
6. Marketing of the program
7. Service on committees

Questionnaires were sent to the RAMS and the labs. Each potential respondent was asked to indicate the amount of time (s)he believed the RAMs spend on each task currently and the ideal amount of time the RAMs should spend on each task to be maximally effective.

In addition, written comments were solicited regarding the tasks, the improvement of communications, and the RAM criteria for selection. The vigorous, intense responses received from headquarters and laboratory personnel underscored the importance of this issue to many individuals in the Command. Thanks to all who took the time to help with this effort.

The results of the survey were enlightening. Opinions of what the RAMS do in their jobs varied greatly not only among RAMs but also among the labs and the individual respondents in the labs.

For example, one of the most important RAM duties as judged by the labs and the RAMs alike is to develop the research program. Responses showed six labs were content with the amount of time they believed RAMs spend on program development (14% currently, 17% ideal). Two labs called for more time to be spent (15% currently, 32% ideal), and one lab wanted less time dedicated to this duty (22% currently, 8% ideal). Although these percent spreads may not appear to be particularly wide, the written comments clearly showed the diversity of opinions reflected in these numbers is very real.

Also very notable was the differences in the opinions among the seven responding lab COs and Scientific Directors. One such response suggested the RAMs should spend only 1% of their time on program development, while another lab senior manager wanted the RAMS to devote 60% of their time on this duty. Clearly, some very important people in our system are telling us that their expectations on the roles of these individuals are strikingly different.

The majority of respondents agreed the RAMs' jobs are too big for any individual and the scope of responsibilities makes it impossible to adequately meet all customers' needs. One respondent indicated the RAMs should spend 300% of their time on all duties inclusive, which most RAMS feel they are already doing!

To help ease this impossible workload, it was suggested by a number of lab respondents that RAMS and scientists work together to accomplish program development, program execution, program defense and the identification of new research topics. This new approach of participatory program management will require RAMS and labs to build mutual trust, communicate with each other, and to be part of a team to build the products required for the operational forces.

Dates To Remember

December 1991

- 7 - 8 Dec: Army/Navy Infectious Disease Overseas Commanders Conference, Bethesda, MD
- 9 - 11 Dec: COs' Strategic Planning Meeting, Bethesda, MD

January 1992

- 1 Jan: Full research proposals for FY94 ARIs and PEs due
- 16 Jan: First interim report for FY92 due

February 1992

- 12 - 13 Feb: Review of Septic Shock Research

March 1992

- 4 - 5 Mar: FY94 ARI briefing/selection

April 1992

- 21 - 23 Apr: SPAWAR Information Exchange Conference, NSWC, White Oak, MD
- 30 Apr: FY91 Annual Report published

INDEPENDENT RESEARCH AND INDEPENDENT EXPLORATORY DEVELOPMENT PROJECTS SELECTED FOR FY92

The selection of IR projects was complicated in FY92 by a 60% Congressional cut to the IR program. The 6.2N program, under which our Independent Exploratory Development is supported, was also marked for cuts by Congress.

The selection of Independent Research (IR) projects, while never a simple process, was definitely made more complex this year by Congressional actions that levied a 60% cut to the IR program. This cut reduced NMRDC's IR allocation from a projected $1272K to $457K and the number of supportable projects from approximately 15 to six (35 IR proposals were received for the FY92 program). The 6.2N program, under which our "Independent Exploratory Development (IED)" is supported, also was "marked" for cuts by the Congress, limiting the number of studies supportable by "IED" (five IED proposals were received for the FY92 program). Unfortunately, we will not know the final budget of either of these programs until after the House Appropriations Committee/Senate Appropriations Committee (HAC/SAC) conference (November 1991).

These very painful cuts in our IR and 6.2N budgets were somewhat offset by an increase in the FY92 funding of our Infectious Disease (ID) Program. A number of very fine ID proposals, originally submitted as IR or IED efforts, were very "sellable" to the core program because of their favorable peer-review in the IR/IED selection process. In FY92, eight proposals submitted as IRs and two proposals submitted as IEDs were fully funded in the core ID program.

Finding support for many of the outstanding ID proposals provided a little "breathing room" in the IR program. Nine IRs were selected for funding, based on the scores and comments provided by both in-house and external peer reviewers. Six of these studies are being funded immediately, while the remaining three efforts may be funded depending on the outcome of the HAC/SAC conference. In addition, fiscal support for two "IED" projects was secured in the 6.2N program. Congratulations to all who participated in the IR/IED competition and to our FY92 IR/IED awardees:

Dr. Steve Kessler (NMRI, IR),

Dr. Florence Rollwagen (NMRI, IR)

Dr. John Schrot (NMRI, IR)

Dr. Che-Hung Lee (NMRI, IR)

Dr. Tamsin Kelly (NHRC, IR)

Dr. Warren Lockette (NHRC,IR)

Dr. Angela Nilius (NDRI, IR)

Dr. Y.-H. Kang (NMRI, IR)

CAPT R.A. Cahill (NMRI, IR)

Dr. John Nevola (NMRI, IED)

LT Karl Van Orden (NSMRL, IED).

In the past few years, we have tried to make the IR/IED selection process as fair a process as possible, by securing the opinions of qualified scientific peer reviewers (68 scientists participated in FY92 review). The scoring of these reviewers drives a prioritization of proposals that is balanced against constraints of the IR program and by any pressing program management concerns. A proposed IR program is provided to the NMRDC Director of Research and Development, who makes the final selection of projects in accordance with the directives established by the Office of Naval Research (ONR, the funding sponsor). Clearly we do not yet have a perfect process that would seem "fair" to all applicants, but we have certainly caught the favorable attention of ONR, which thinks that *"NMRDC's new centralized project selection and funding allocation procedure, based on proposal ranking at the Command level, should increase overall IR program quality."* *

*Department of the Navy, Independent Research Independent Exploratory Development IR/IED Program Report - FY90, July 1991.

PERSONNEL NOTES:

Naval Health Research Center

CAPT Thomas Jose Contreras, Executive Officer of the Naval Health Research Center, San Diego, CA, received the 1991 Professional Achievement in Government Award from the Hispanic Engineer National Achievement Awards Committee. The Achievement Awards were created to pay tribute to outstanding Hispanics for their contributions in science, engineering, education and technology. Along with 17 other winners, CAPT Contreras participated in a nationally televised one-hour special titled, "Success Through Education: A Salute to Hispanic Excellence".

Naval Biodynamics Laboratory

CAPT. D.W. Call had the pleasure of swearing in **Edward E. Taylor** as an Ensign in the Medical Corps. In 1989 Ensign, (then HM2) Taylor was named the Sailor of the Year for the Naval Biodynamics Laboratory, New Orleans, LA, and its parent Command the Naval Medical Research and Development Command headquartered in Bethesda, MD. Ensign Taylor is now attending Louisiana State University School of Medicine in Shreveport, LA under an Armed Forces Health Professions Scholarship.

NAVY MEDICAL R&D, CAN WE LET INDUSTRY AND UNIVERSITIES DO IT FOR US?

by CDR R. Carter, MSC, USN, Director for Research and Development

Question: *Why not let industry and universities do all of Navy medical R&D?*

This question was recently asked by a staff member of our biggest sponsor, the Office of Advanced Technology (OAT). Many people at all levels of government think industry and universities offer distinct advantages over the in-house laboratories for medical R&D. Congress is often influenced in this direction because industry and universities are constituents in more districts and states than are in-house Navy medical research laboratories. OAT has to be able to convince the Congress that NMRDC's research program and its contract process is balanced, designed to obtain the best information, and open to these constituents. This is especially the case in austere times, and when lobbyists publish announcements in journals that there is a *"treasure house of military medical R&D funding available from NMRDC"*.

Contract research is popular in the Congress because of the direct applicability and ease of transfer of research findings or products to both military and civilian sectors of society. In addition, contract performance of Navy medical R&D in universities and in military medical teaching facilities may facilitate incorporation of the latest results of military medical R&D into the curricula. Examples of programs with dual civilian and military use include:

- National Marrow Donor Registry
- Blood and Blood substitute program at the Naval Blood Research Laboratory, Boston, MA.
- Liposome encapsulated hemoglobin research involving VESTAR, SOMATOGEN, City of Hope, Naval Research Laboratory and the University of Texas
- Advanced wound repair techniques using tobramycin impregnated polymethylmethacrylate beads at the University of Louisville, KY

Proponents reason that if these types of contract programs are good for relations with the Congress, then a total medical R&D contract program would be better.

Answer: *Balance in our program is the only way to effectively meet all our requirements.*

NMRDC sent $24 million to industry and universities in FY 91, not including our support of the National Marrow Donor Program. This amounts to about a fourth of our total funds. In contrast, universities perform 23% of the OAT sponsored non-ATD R&D while industry performs another 15%. Industry and universities get virtually all the ATD money provided by OAT.

We strongly believe industry and universities should not do all of Navy medical R&D because the in-house laboratories perform several important functions which complement the capabilities of industry and universities but cannot be duplicated by them. First and most important, the laboratories are reservoirs of personnel who are familiar with Navy operations and who are able to apply the latest biomedical technologies to military contingencies. A spectacular example is the work in support of operations Desert Shield/Storm and the rapid response of the biomedical in-house laboratory system.

There are several types of biomedical R&D that are better accomplished in Navy facilities. The laboratories represent our only capability to work in areas with special requirements and sensitivities. For example:

- Radio-frequency dosimetry
- Sustained/enhanced performance studies
- Classified projects

In addition, the laboratories perform work in areas that have no viable commercial market and little intrinsic scientific appeal to industry and universities but are vital to military capabilities and operations. For example:

- Military aviator selection
- Diving decompression
- Infectious diseases prevalent in the third world

The laboratories have developed special expertise in applying biotechnology to military problems in areas relatively unattractive to industry and universities. Our medical R&D facilities have world-leading capabilities in a variety of areas, for example:

- Application of polymerase chain reaction to biological defense
- DNA typing of blood and tissues
- Toxicological evaluation of military-unique substances and situations
- Photogrammetry for biodynamics
- Sensory physiology of vision
- Hearing and the vestibular system
- Isolation of stem cells
- Psychobiology of work-sleep cycles

We believe it is only prudent to exploit advantages wherever we find them, both in-house and through contracts. It is wasteful to limit our program to industry or universities when our laboratories have the capability or other comparative advantage.

NRL TECHNOLOGY TRANSFER AWARDEES

Drs. Frances S. Ligler and Alan S. Rudolph of the Center for Bio/ Molecular Science and Engineering at the Naval Research Laboratory (NRL), Washington, DC, received the NRL Technology Transfer Award for their research and development efforts with the oxygen carrying red cell substitute, liposome encapsulated hemoglobin (LEH).

With funding support through the Office of the Chief of Naval Research and NMRDC, the investigators have been the driving force in moving their basic research efforts to more advanced preclinical studies in collaboration with biotechnology firms. The major companies involved include Somatogen, responsible for producing a genetically cross-linked recombinant human hemoglobin, and Vestar, a leading liposome technology firm capable of encapsulating the hemoglobin in one micron diameter lipid spheres.

The ultimate goal of the development effort is to provide a safe and efficacious red cell substitute for used in transfusion emergencies in a combat casualty contingency without depending on current methods of human red cell collection, processing, and matching.

For technology transfer purposes, a conscious effort to publicize the LEH effort in the scientific community was undertaken in FY89 to attract companies and academic collaborators. An overview of the LEH effort was presented by Dr. Ligler at the International Meeting on Red Cell Structure and Metabolism and was published in Red Cell Structure and Metabolism, George Brewer (ed.). Dr. Ligler organized and hosted two-day symposia on LEH in 1989 and 1990. Dr. Rudolph presented invited talks at the International Blood Substitute Meetings and at the International Membrane Technology Conference. Dr. Rudolph recently presented at the 4th International Blood Substitutes Meeting and serves on its International Scientific Advisory Committee. The NRL group published six referred papers and two invited book chapters on LEH since 1989 and three more scientific papers on the subject are submitted for publication.

A very significant effort has been dedicated to enhancing the LEH patent portfolio due to its importance in inducing corporate commitment to the project. The U.S. patent on the LEH composition was allowed in September 1989. Additional patents on use and variations have also been filed. The NRL research team and Office of Naval Research attorneys are engaged in discussions with Somatogen and Vestar concerning mechanisms for patent licenses, as well as goals and conditions for agreements. Licenses for the first patents are expected to be awarded in the spring.

FOUR ARIs COMPETE FOR FY94 FUNDING

NMRDC completed the review of preproposals submitted as candidate FY94 Accelerated Research Initiatives (ARI). In all, 14 preproposals were submitted from NAMRL (5), NBDL (1), NMRI (2), NSMRL (5) and BUMED (1), making this our largest input of ARI ideas ever. Four preproposals were selected to advance into the ARI competition:

- "Evoked Otoacoustic Emissions and Inner-Ear Damage from Noise Exposure (Dr. Lynne Marshall, NSMRL)
- "The Role of Cytokines in Recovery from Enteric Compromise Following Hemorrhagic Shock" (Dr. Florence Rollwagen, NMRI)
- "Development of High Affinity, Monovalent, ABO-Group Blocking Reagents for the Prevention of Transfusion Reactions and the Use of Red Blood Cells without ABO Typing" (CDR Lyn Yaffe, BUMED)
- "Characterization of Visual Target Detection on Sonar Displays" (Dr. Joseph DiVita, NSMRL)

These exceptional research ideas will be developed into full research proposals which will be reviewed by a committee of external scientific experts and Navy requirement/ transition specialists. The review committee will receive briefings by the principal investigators on 5 - 6 March 1992 and will select the single ARI to be funded in the FY94 program. Criteria for the down-selection of research preproposals include: the work must be basic (appropriate for 6.1 funding); must meet the Office of Naval Research's (ONR) definition of an ARI (research that benefits from a short term accelerated investment to capitalize on scientific opportunities or respond to a critical Navy requirement); must address a problem that is optimally addressed by the Navy medical community (vice by ONR science officers, by an alternate Service, etc.); and must be compatible with NMRDC's investment strategy. Additionally, the preproposal must convince that the proposed work is executable relative to the scope of research described, the duration, and the amount of funding requested.

NMRDC INVESTIGATORS' CONFERENCE SURVEY COMPLETED

by Christine Eisemann, Associate Director for Research Management

During a number of recent management conferences (NMRDC Scientific Advisory Board, Pensacola, FL, August 1989; Strategic Planning Retreat, Baltimore, MD, April 1991) it was suggested that NMRDC conduct an annual scientific meeting where laboratory investigators could meet and discuss research interests and experiences. Potentially, such a workshop would lead to an increased understanding of the professional capabilities and resources throughout the system and to increased research collaboration among the scientists who are the heart of this research organization.

The first step in developing an "NMRDC Investigators' Conference" was to determine whether the investigators would be interested in attending the proposed meeting, and if so, what format would provide maximal benefit. In order to answer these questions, the Strategic Planning Advisory Group established a subcommittee to tackle the problem of collecting opinions from a cross-section of scientists from the various labs and programs within our Command.

The Advisory Group subcommittee,

LCDR Trevor Jones, chairman (NMRI)

Dr. Thomas Doubt (NMRI)

LCDR David Kobus (NHRC)

LT David Neri (NAMRL)

LT Karl Van Orden (NSMRL)

Dr. Angela Nilius (NDRI)

Dr. David Matson (NBDL)

teamed-up to develop, distribute, and collect completed questionnaires for analysis. Theirs was a job very well done, and the entire Command extends a **BRAVO ZULU** for their efforts.

LCDR Jones, who statistically analyzed the entire data collection, reported that a total of 185 questionnaires (from 10 labs and detachments) were completed and many of them contained extensive comments on the concept of an investigators' conference. Responses were analyzed, using student's t tests, according to the respondent's degree, discipline, rank, years of research experience, and years working within NMRDC.

The questionnaire results showed that the majority of NMRDC scientists (irrespective of degree, years of research experience, etc.) favor the development of a short, two-day meeting for NMRDC investigators and think that such a meeting would significantly improve mission effectiveness. They believe it is important to know about the work of others within NMRDC and to increase collaboration, especially in areas of closely related work.

There was no consensus on the format of the meeting, however, and it was clear that such a meeting would take second place to an opportunity to attend an additional, national scientific meeting. Although respondents thought that managers should not necessarily be excluded from the proposed NMRDC meeting, it was clear that they judged bench-level, hands-on experimenters to be the most important conference attendees.

NMRDC'S ROLE IN THE CONTRACT PROCESS

by CDR R. Carter, Director for Research and Development

Industry and universities are ill-equipped to elicit, interpret and prioritize Navy requirements, nor can they be honest brokers to select performers of Navy medical R&D. This role is carried out by the Navy Medical Research and Development Command (NMRDC) and is a complement to industry's and universities' capabilities to meet Navy requirements for biomedical research.

Program integration is a major function of the Command. Integration is necessary across performers, sponsors, research areas, Navy mission areas (described in Naval Warfare Publication 1, revision A) and time and NMRDC strikes a proper balance between contract and in-house programs. Research in a new area is best done via contract if the duration of the research is anticipated to be short or episodic. It is more cost effective to develop an in-house capability for continuing work in a reserach area. Some Navy biomedical requirements can be developed by industry as low-margin commercial products at great savings to the Navy once they are shown to be feasible. Since industry is reluctant to attempt the development of some products because of the risk of failure and consequent business loses, the Navy can assume the risk of developing such products by sponsoring risk-reducing industrial R&D to establish the feasibility of the products. These products then become available for dual use in the military and civilian sectors of society.

NMRDC's Advanced Technology Demonstrations in Liposome Encapsulated Hemoglobin and in Combat Would Healing are examples of Navy medical R&D contracts priming the pump of industry to produce products based on concepts which were considered too risky and unprofitable by industry. Such contract research offers the Navy the prospects of an occasional big win. In retrospect, such research shows clearly what technologies work and which do not in particular Navy applications.

EFFICIENCY REVIEWS FOR LABORATORIES

The Secretary of the Navy requires all Naval shore commands to perform an Efficiency Review (ER) once every five years. The process involves a top down, organizational and billet review. All Officer, Enlisted and Civilian positions are reviewed for proper grade, classification and place in the organization. The result is a credible and defensible shore manpower document. NMRDC has already completed three reviews (NMRDC, NSMRL, NMRI). The remaining six activities will conduct their ER's in consecutive order from 1 Jan 92 to 1 Apr 93. Each ER process should take no more than three months to complete.

Efficiency Review Start Dates By Activity

Activity	Start Date	Completion Time
Naval Aerospace Medical Research Laboratory	1 Jan 92	60 days
Naval Biodynamics Laboratory	1 Apr 92	60 days
Naval Health Research Center	1 Jun 92	60 days
Naval Medical Research Unit 3 (Cairo)	1 Sep 92	90 days
Naval Medical Research Unit 2 (Jakarta) and Manila Detachment	1 Jan 93	90 days
Naval Dental Research Institute	1 Apr 93	60 days

THE SCIENTISTS-AT-SEA PROGRAM PARTICIPANTS

The Scientists-at-Sea Program provides a unique opportunity for individuals from our laboratories to meet and interact with the customers of our technology programs. The program is open to any laboratory employee, including scientists, engineers, administrative personnel, and others recommended by the Command. Deployments last for two to five days at sea on a cruiser, destroyer or amphibious ship (aircraft carriers and submarines are not included) . The ships are usually docked at Norfolk, VA or another Navy base on the East Coast. Many people from our labs have now gone on one of these short deployments and had the opportunity to tour the functional areas and to view crew activities and living conditions.

Lt. A. Richards, MSC, USN, Principal Investigator, Rickettsial Diseases Program, NMRI, Bethesda, MD aboard the USS Gunston Hall (LSD-44) out of Norfolk: *"Since our jobs as scientists in the Navy are to help those in the Fleet, the shipboard experience will influence my work."*

Bernice Kaufman, Research Biomedical Engineer, NBDL, New Orleans, LA aboard the USS Puget Sound out of Norfolk: *"The trip has made our customers more concrete in my mind. I gained greater awareness of ship motion problems, both those I experienced and those discussed by the crew (e.g. interference with Combat Information Center tasks). Most importantly, I would more readily contact operational parts of the Navy regarding their needs or feedback with regards to research in either our ship motion or impact acceleration programs."*

Mark Lotz, Electronics Engineer, NBDL, New Orleans, LA aboard the USS Gunston Hall (LSD-44) out of Norfolk: *"While at sea most of my time was spent observing general shipboard activity. There were two General Quarters drills that I observed. The most interesting activities were watching Land Craft-Air Cushion's (LCAC) practicing landings on the ship and watching operational testing of the ship's defense systems. The Close-in Combat Weapon System guns and several chaff canisters were fired. One memorable highlight of my trip was riding on a LCAC during night-time landing practice."*

Shirley P. Stewart, Budget Analyst, NDRI, Great Lakes, IL aboard the USS Puget Sound out of Norfolk: *" It was an opportunity to see firsthand what they Navy is all about and an opportunity I probably would never have again. I work mostly with military and when they talk about living on a ship I can understand a little better what they are talking about. I was able to tour almost every area of the ship and always with an excellent guide. Everyone was friendly, informative and helpful. "*

Lloyd Simonson, Scientific Director, NDRI, Great Lakes, IL aboard the USS Guadalcanal (LPH-7) out of Norfolk: *"Captain Highfill and his XO Captain Turville allowed us to see the ship from stem to stern and top to bottom. Dr. deTorres, the ship's Medical officer, provided a tour of the medical department and LT J. Bernanrdy led a tour of the dental department. Performing surgical procedures and practicing dentistry on a moving ship is a challenge that can only be learned by sea experience. The Scientists-at-Sea Program was a really positive experience. It allowed us to communicate with our fellow scientists as well as gain a new appreciation for the Navy and its dedicated personnel."*

For more information contact NMRDC Code 04A.

NOTES FROM THE INTELLECTUAL PROPERTY COUNSEL

by A. David Spevack, Intellectual Property Counsel

What Is Government Property

In the area of Government property disposal, the Navy's requirements are outlined in subchapter D of 32 code of Federal Regulations section 736.1 at SECWAR. What constitutes Government property? Essentially everything bought by or for the Government or made by or for the Government by contractors or Government employees is Government property and can only be disposed of in accordance with the specific government disposal rules. Technically every computer disk bought by the Government, every microbiological sample created by Government employees, every publication printed at Government expense is Government property. Of course, we couldn't carry on our ordinary business unless we could give away reprints or copies of information. The disposal of this type of information falls under the various regulations which require us to help the public.

A more difficult problem arises with respect to biological samples. It is recognized that sending biological samples to fellow scientists is a regular part of scientific research and it would be best if the transfer or disposal of this Government property was covered by a proper agreement. The physical material of a cell line, growth medium, cells, person hours to create the sample, etc., can be of rather small value. But the worth of the cell line can also be valued by what it can do, such as creating a unique antibody of great commercial value. A congress of technology managers of universities have prepared a model microbiological sample agreement which allows the exchange of microbiological samples for research purposes but preserves to the originator the commercial applications. Counsel is now in the process of modifying the university agreement for use by NMRDC. In the past requests for special agreements have been provided in particular situations. Also note that transfer of microbiological samples outside of the country may require export licenses from the Department of Commerce.

Who Can Sign Publication Release Forms

There are very strict rules and regulations defining who has signature authorization for the Government to release scientific articles for publication. Keep this in mind, if you wrote the article as part of your Government duties or if it is related to Government duties, the article cannot be covered by copyright and you cannot sign an agreement which gives this nonexistent copyright to a publisher. Most publishers have an alternate release for articles prepared by a Government employee, these releases are signed by the Commanding Officer or the Reviewing Authority.

Copyrights For Government Owned Computer Programs

In September 1991 testimony was heard before the Senate Committee on Commerce, Science and Transportation (S1581) that would amend the Federal Technology Transfer Act of 1986 (Stevenson-Wydler Act) to provide copyright protection for work related computer programs produced by Government employees. The act will only protect programs written as part of a Cooperative Research and Development Agreement. Prior to this amendment the only protection for programs was filing a patent application that claimed the program as part of a claim to an apparatus or process of operating an apparatus.

Freedom Of Information Act Requests For Government Computer Programs

The floppy disk or hard disk on which an operating program is stored is not considered a Government document as defined under the Freedom of Information Act but it is considered Government property. Some Commands have "sold" Government computer programs under the Technology Transfer Act. Sheets of paper which might record the code for the computer program are a Government record and such a record is obtainable under the Freedom of Information Act.

Drug Abuse Testing

The case of AFGE v. Cheney was decided by the 9th Circuit Court of Appeals on September 10, 1991. The Court held that the Navy has a compelling interest in the identification of illegal drug abuse by employees holding security clearances, and that the Navy's random testing of employees holding a Top Secret Clearance with Access (TSA) is constitutional.

Ethics

New ethics regulations are in the process of being issued by the Office of Government Ethics. Questions concerning the new ethics regulations should be directed to the JAG office at the Host Command. Questions relating to intellectual property and general ethics questions can be direct to Code 00L, NMRDC (301)295-6759.

Search of Patent Literature

The preparation of a good protocol for a new research project requires a complete search of the scientific and patent literature. Counsel will assist in a computer search of the patent literature from 1975 to date.

HIGHLIGHTS OF NMRDC RESEARCH

Researchers Study Biological Effects Of Locally Administered Cytokines With Unique Cytokine-agarose Block Model

Cytokines, a diverse group of secreted cellular molecules (cytokines are also called lymphokines, monokines, interleukins and interferons), are produced by a wide variety of cells. Cytokines have been used clinically to enhance the immune competence of individuals against certain tumors and infections but treatment with these immune modulators is restricted due to their many adverse side effects. In order to reach effective local concentrations, the systemic dose required approaches toxic levels. Researchers in the Enteric Disease Program, at the Naval Medical Research Institute, Bethesda, MD, developed a unique in vivo murine model for the local delivery of cytokines which mimics the direct production of cytokines at an infection- or wound- site. This model uses implanted agarose blocks to administer cytokines to specific tissues in vivo. Cells attracted to the blocks are harvested and cultured in vitro so researchers can study the kinetics and phenotypes of cells (neutrophils, lymphocytes, and macrophages) attracted by the cytokines as well as the functions (phagocytosis and cytokine production) of these cells. The cytokine-agarose block model provides a new capability for studying cytokine control of local immune responses that are important for the elimination of microbial infections, the control of tumor growth and the enhancement of wound repair.

Evaluation Of Cognitive Performance Following Substance Abuse

Various research studies have shown that alcohol abuse impairs an individual's ability to perform tasks in general and has specific detrimental effects on cognitive performance. Alcoholics who remain abstinent will evidence substantial cognitive recovery, however, the question remains as to whether cognitive capacity returns to pre-abuse levels. Although alcoholics treated by the Navy are given formal treatment at Navy Alcohol Rehabilitation Centers (NARCs) and are encouraged to abstain from alcohol, no testing is done to ensure they are cognitively fit to return to duty. Researchers in the Cognitive Performance and Psychophysiology Department, Naval Health Research Center (NHRC), San Diego, CA, are currently evaluating the use of event-related brain potentials (ERPs) as a tool for measuring various aspects of cognitive performance. Using ERP component parameters as a measure enables the functional aspects of cognition (filtering, discrimination, memory encoding, memory retrieval, and decision making) to be observed. The optimal performance of many Navy jobs requires that these abilities be intact. A one-year longitudinal study has been conducted on alcoholics at NARC, San Diego, in order to identify changes in ERPs that may occur during rehabilitation. The results of this reserach may lead to an objective method for tracking cognitive rehabilitation.

Progress Toward A Malaria Vaccine

Malaria, a serious parasitic disease spread by Anophiline mosquitoes, kills more than one million of the 270 million people infected each year and is a major threat to deployed troops in endemic areas. The single-cell parasite responsible has a complex life cycle that makes it a difficult vaccine target. Since the parasite changes during its life cycle, vaccines that work against one stage may not work against others. The ideal vaccine would target every stage of the malaria infection. In a major step toward development of a comprehensive human vaccine, researchers in the Malaria Program at the Naval Medical Research Institute (NMRI), Bethesda, MD, have successfully inoculated laboratory mice with a dual-action vaccine that targets two key proteins on the malaria parasite. The two proteins are the circumsporozoite (CS) protein and sporozoite surface protein 2 (SSP2), which was recently discovered at NMRI. NMRI researchers believe that the vaccine stimulates cytotoxic T cells to attack the parasites in the liver; antibodies produced against the CS and SSP2 proteins also may be inhibiting sporozoites. The mouse vaccine is not directly applicable to humans, but researchers believe a vaccine that targeted these same proteins on the human malaria parasites would be equally effective. They are currently working on identifying the human malaria parasite counterpart of SSP2 and on developing effective ways of delivery to humans.

Trypsin Detection And Quantitation Using The BAPNA-in-Agar Gel

Researchers at the Naval Dental Research Institute, Great Lakes, IL, developed a quantitative assay for measuring trypsin and trypsin-like enzyme activities using N-*a*-benzoyl-DL-arginine-*p*-nitroanilide (BAPNA). Both cultured oral microorganisms and human subgingival plaque can be screened and evaluated for trypsin activity. Thus far, use of the BAPNA-in-Agar system has revealed a positive reaction by trypsin and several Gram-negative oral microorganisms associated with adult periodontal diseases. Applied clinically, the test will help identify patients undergoing changes in disease status and will be useful in monitoring the success of therapeutic measures. Exploratory tests with the subgingival plaque samples indicate the BAPNA-in-agar system can serve as a rapid, simple method for detecting microbial trypsin-like activity.